PATENT
Customer No. 22,852
Attorney Docket No. 06530.0309

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
David I. FREED	Group Art Unit: 3739
Application No.: 10/760,520	Examiner: Kasztejna, M.
Filed: January 21, 2004	Confirmation No.: 1095
For: ENDOSCOPIC DEVICE HAVING SPRAY MECHANISM AND RELATED METHODS OF USE	

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL OF APPEAL BRIEF (37 C.F.R. 41.37)

Transmitted herewith is the APPEAL BRIEF in this application with respect to the Notice of Appeal filed on January 7, 2008.

This application is on behalf of

☐ Small Entity ☒ Large Entity

Pursuant to 37 C.F.R. 41.20(b)(2), the fee for filing the Appeal Brief is:

☐ $255.00 (Small Entity)

☒ $510.00 (Large Entity)

TOTAL FEE DUE:

Appeal Brief Fee	$510.00
Extension Fee (if any)	$120.00

☒ The fee total of $630.00 is submitted herewith.

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this Appeal Brief, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to Deposit Account 06-0916.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 2, 2008

By: _____

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Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed January 7, 2008, and further to Board Rule § 41.37, Appellant presents this brief and encloses herewith a check including the fee of $510.00 required under 37 C.F.R. § 41.20(b)(2).

This Appeal is in response to the final rejection of claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93 and 97-102 in the Office Action mailed September 5, 2007 and the Notice of Panel Decision from Pre-Appeal Brief Review mailed January 22, 2008. The deadline for filing this Brief extends to April 7, 2008, by a Petition for Extension of Time for one (1) month, filed herewith. The fee of $120.00 required under 37 C.F.R. § 1.17(a)(1) for the extension of time is also enclosed.

If any additional fees are required or if the enclosed payment is insufficient,

Appellant requests that the required fees be charged to Deposit Account No. 06-0916.

TABLE OF CONTENTS

Real Party in Interest

Boston Scientific Scimed, Inc. is the real party in interest, as reflected in the Notice of Assignee Name Change filed July 21, 2005. Boston Scientific Scimed, Inc. is a wholly-owned subsidiary of Boston Scientific Corporation.

Related Appeals and Interferences

There are currently no other appeals or interferences of which Appellant, Appellant's legal representative, or assignee are aware, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-7, 10-21, 23-37, 39-53, 56-64 and 66-102 are pending in the application, as claims 8, 9, 22, 38, 54, 55 and 65 are canceled without prejudice or disclaimer.

Of the pending claims, claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92 and 94-96 are withdrawn from consideration.

The remaining claims, claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93 and 97-102, are rejected.[1]

The rejections of claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93 and 97-102 are appealed, although allowance of withdrawn claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92 and 94-96 is also requested, inasmuch as each of these claims depends on an allowable independent claim.

[1] Although the Notice of Panel Decision from Pre-Appeal Brief Review mailed January 22, 2008, does not indicate the status of claim 93, Appellant understands that claim 93 is rejected based on the Office Action mailed September 5, 2007, and the Advisory Action mailed December 17, 2007.

Status of Amendments

Subsequent to the final rejection in the Office Action mailed September 5, 2007, an Amendment after Final was filed December 4, 2007. The Advisory Action mailed December 17, 2007, indicates that the Amendment after Final is entered for purposes of appeal.

Summary of Claimed Subject Matter

The invention relates generally to a medical device and a method of performing a medical procedure using a medical device.[2]

With respect to independent claim 1, an embodiment of the invention is directed to a medical device (10) including a proximal handle (30), and an elongated member (20) having a proximal end, a distal end, and a lumen therebetween. *See* Figures 1-6 and paragraphs [023]-[025]. The proximal end is coupled to the proximal handle (30). *See* paragraph [025]. The elongated member (20) is sufficiently flexible to traverse through tortuous anatomy of a patient's body. *See* paragraph [025]. An end effector consists essentially of a snare loop (40) proximate the distal end of the elongated member (20). *See* paragraphs [030], [031], [038], [040] and [041]. Actuation of the proximal handle (30) causes the snare loop (40) to sever tissue. *See* paragraph [041]. A distal member (50) is configured to open and substantially close the distal end of the lumen. *See* paragraphs [033], [034], [038] and [039]. The distal member (50) defines a flow path such that, when the distal member (50) substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member (20). *See* paragraphs [024], [027], [028] and [033]-[038].

[2] In referring to the specification and drawings, Appellant does not intend to limit the scope of the claims to the exemplary embodiments described in the specification and shown in the drawings. Rather, Appellant is entitled to have the claims interpreted broadly to the maximum extent permitted by statute, regulation, and applicable case law. In addition, the references to the specification and drawings are exemplary and non-exhaustive.

With respect to independent claim 34, an embodiment of the invention is directed to a medical device (10) including an elongated member (20) having a proximal end, a distal end, and a lumen. *See* Figures 1-6 and paragraph [024]. The elongated member (20) is sufficiently flexible to traverse through a tortuous anatomy of a patient's body. *See* paragraph [025]. An end effector consists essentially of a snare loop (40) proximate the distal end of the elongated member (20). *See* paragraphs [030], [031], [038], [040] and [041]. The end effector is configured to sever tissue. *See* paragraph [041]. A nozzle member [50] is configured to substantially seal the distal end of the lumen. *See* paragraphs [033], [034], [038] and [039]. The nozzle member (50) defines a flow path in fluid communication between the lumen and an outside of the elongated member (20) when the distal end of the lumen is sealed with the nozzle member (50). *See* paragraphs [024], [027], [028] and [033]-[038].

With respect to independent claim 47, an embodiment of the invention is directed to a method of performing a medical procedure. *See* paragraph [038]. The method includes inserting a medical device (10) into a tissue tract of a patient. *See* Figures 1-6 and paragraph [041]. The medical device (10) includes a lumen (20) and a nozzle member (50) configured to substantially seal a distal end of the lumen. *See* paragraphs [024], [027], [028] and [033]-[038]. The nozzle member (50) defines a flow path in fluid communication between the lumen and an outside of the lumen when the distal end of the lumen is sealed with the nozzle member (50). *See* paragraphs [024], [027], [028] and [033]-[038]. The medical device (10) further includes an end effector consisting essentially of a snare loop (40) coupled to the nozzle member (50). *See* paragraphs [030], [031], [038], [040] and [041]. The distal end of the lumen is closed with the nozzle

member (50), fluid is sprayed through the flow path of the nozzle member (50) and onto tissue of the tissue tract to enhance visualization of tissue of the tissue tract, and the end effector of the medical device (10) is actuated to sever the tissue of the tissue tract. *See* paragraphs [035] and [038]-[041].

With respect to independent claim 59, an embodiment of the invention is directed to a method of performing a medical procedure. *See* paragraph [038]. The method includes inserting a medical device (10) into a patient. *See* Figures 1-6 and paragraph [041]. The medical device (10) includes an elongated member (20) having a proximal end, a distal end, and a lumen, the distal end extending into the patient. *See* paragraphs [023]-[025]. The medical device (10) further includes an end effector consisting essentially of a snare loop (40) proximate the distal end of the elongated member (20). *See* paragraphs [030], [031], [038], [040] and [041]. The medical device (10) still further includes a distal member (50) coupled to the end effector and configured to substantially seal the distal end of the lumen, the distal member (50) defining a flow path in fluid communication between the lumen and an outside of the elongated member (20) when the lumen is sealed with the distal member (50). *See* paragraphs [024], [027], [028] and [033]-[038]. Fluid is injected through the distal member (50) of the medical device. The end effector is actuated to sever tissue of a tissue tract. *See* paragraphs [035] and [038]-[041].

With respect to independent claim 69, an embodiment of the invention is directed to a medical device (10) including a proximal handle (30) and an elongated member (20) having a proximal end, a distal end, and a lumen therebetween. *See* Figures 1-6 and paragraphs [023]-[025]. The proximal end is coupled to the proximal handle (30).

See paragraph [025]. The elongated member (20) is sufficiently flexible to traverse through tortuous anatomy of a patient's body. *See* paragraph [025]. An end effector (40) is proximate the distal end of the elongated member (20). *See* paragraphs [030], [031], [038], [040] and [041]. Actuation of the proximal handle (30) causes the end effector (40) to perform a medical procedure. *See* paragraph [041]. A distal member (50) is configured to open and substantially close the distal end of the lumen. *See* paragraphs [033], [034], [038] and [039]. The distal member (50) defines a flow path (155) such that, when the distal member (50) substantially closes the distal end of the lumen, the flow path (155) enables a flow communication between the lumen and an outside of the elongated member (20). *See* Figure 8A and paragraphs [024], [027], [028] and [033]-[038]. At least a portion of the flow path (155) has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet (151) of the flow path and a cross-sectional flow area of an outlet (159) of the flow path. *See* paragraph [037].

With respect to independent claim 87, an embodiment of the invention is directed to a medical device (10) including a proximal handle (30) and an elongated member (20) having a proximal end, a distal end, and a lumen therebetween. *See* Figures 1-6 and paragraphs [023]-[025]. The proximal end is coupled to the proximal handle (30). *See* paragraph [025]. The elongated member (20) is sufficiently flexible to traverse through tortuous anatomy of a patient's body. *See* paragraph [025]. An end effector (40) is proximate the distal end of the elongated member (20). *See* paragraphs [030], [031], [038], [040] and [041]. Actuation of the proximal handle (30) causes the end effector (40) to perform a medical procedure. *See* paragraph [041]. A distal member (50) is configured to open and substantially close the distal end of the lumen. *See*

paragraphs [033], [034], [038] and [039]. The distal member (50) defines a flow path (255) such that, when the distal member (50) substantially closes the distal end of the lumen, the flow path (255) enables a flow communication between the lumen and an outside of the elongated member (20). *See* Figure 8B and paragraphs [024], [027], [028] and [033]-[038]. The flow path includes an inlet and a plurality of outlets (259) connecting to the inlet. *See* paragraph [037].

Grounds of Rejection

A. Claims 1-4, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67 and 97-100 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,682,599 to Konomura (referred to as "Konomura") in view of U.S. Patent No. 6,660,011 to Levinson (referred to as "Levinson").

B. Claims 5-7 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of U.S. Patent No. 5,599,324 to McAlister et al. (referred to as "McAlister").

C. Claims 69-75, 81, 82, 89, 93 and 101 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of U.S. Patent No. 5,871,440 to Okada (referred to as "Okada").

D. Claims 87, 88 and 102 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of U.S. Patent No. 4,204,528 to Termanini (referred to as "Termanini").

Arguments

A. The Rejection of Claims 1-4, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67 and 97-100 over Konomura in View of Levinson

Claims 1-4, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67 and 97-100 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson. These claims are allowable for at least the following reasons.

(i). The Combination of Konomura and Levinson Does Not Disclose or Suggest "an End Effector Consisting Essentially of a Snare Loop," as Recited in Independent Claims 1, 34, 47 and 59

The combination of Konomura and Levinson does not disclose or suggest at least the claimed features of "an end effector consisting essentially of a snare loop," actuated or configured to sever tissue, as recited in each of independent claims 1, 34, 47 and 59.

(a). Novel Aspects of the Claimed Invention

Embodiments of the present invention, as recited in these independent claims, include a novel and non-obvious combined cutting and spraying mechanism in a single device. It permits, by way of non-limiting example, spraying fluid from a distal nozzle to mark a polyp, and then removal of the marked polyp by a snare loop.

For example, as shown in Appellant's Figures 2 and 6, the snare loop (40) is relatively small and takes up relatively little space within the lumen of the tubular member (20) of the device (10). Since the end effector of the device is only a snare loop, the device uses only one control member (25) to actuate the snare loop, and this

control member also occupies relatively little space within the lumen. As a result, even when the snare loop and the control member are disposed in the lumen, there is little inhibition of fluid flow through the lumen to the nozzle (50). A basic and beneficial characteristic of the claimed invention, therefore, is a snare loop that both does not inhibit spraying of fluid when disposed in the device and simply cuts tissue.

(b). Rejection in the Office Action

In the final Office Action mailed September 5, 2007, the Examiner concedes that Konomura does not disclose an "end effector wherein actuation of the proximal handle causes the end effector to sever tissue." *See* page 3 of the Office Action. However, the Examiner asserts that "Levinson teaches of a set of wires 28 that is a snare loop and functions as the tissue cutting end effector" and that "[t]he first set of wires 20 are not part of the *tissue cutting* end effector of Levinson. The first set of wires 20 are used for capturing and retrieving the cut tissue and have no affect on the tissue cutting performed by wires 28." *See* page 8 of the Office Action (emphasis in original). Thus, the Examiner seems to assert that Levinson discloses "an end effector consisting essentially of a snare loop." The Examiner then concludes that because "Levinson teaches of an analogous medical device used for tissue cutting and retrieval," "[i]t would have been obvious . . . to have a tissue cutting end effector [of Levinson] in the apparatus of Konomura." *See* page 3 of the Office Action. Appellant disagrees.

(c). "Consisting Essentially of"

As set forth in M.P.E.P. § 2111.03, "[t]he transitional phrase consisting essentially of limits the scope of a claim to the specified materials or steps, and those that do not materially affect the basic and novel characteristic(s) of the claimed

invention." Citing *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Thus, the recitation of "an end effector consisting essentially of a snare loop" excludes any prior art end effector that includes one or more elements in addition to a snare loop that materially affect the basic and novel characteristics of a snare loop. In this case, the end effectors of Konomura and Levinson each include at least one additional element (i.e., additional to a snare loop) that materially affects the basic and novel characteristics of a snare loop and, therefore, do not disclose or suggest "an end effector consisting essentially of a snare loop."

(d). The Recognized Deficiencies of Konomura

Konomura discloses a basket forceps assembly 1 including a hollow sheath 2 and a basket 3 that moves out of and into the front end of sheath 2 for holding or fracturing a foreign matter. *See* from column 2, line 58 to column 3, line 2. Basket 3 includes a plurality of resilient wires 6 and a front end tip 7 to which the front ends of wires 6 are secured. *See* column 3, lines 8-16. The Examiner alleges that resilient wires 6 correspond to the recited "end effector." The Examiner acknowledges, however, that "Konomura is silent with respect to a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue." *See* page 3 of the Office Action. Indeed, none of resilient wires 6 of Konomura is a snare loop for severing tissue. Therefore, as recognized by the Examiner, the alleged end effector of Konomura does not disclose "an end effector consisting essentially of a snare loop."

(e). Levinson Does not Remedy the Deficiencies of Konomura

The Examiner nonetheless relies on Levinson as allegedly disclosing "an end effector consisting essentially of a snare loop." *See* page 3 of the Office Action. Appellant disagrees. Instead, Levinson seeks to solve the problem of using two separate, different instruments: one instrument to cut tissue and a second, different instrument to retrieve the cut tissue. Levinson's device therefore includes a cutting snare that is necessarily incorporated into a retrieval basket configuration, so that cutting and retrieval occur without removal of the cutting snare from a patient's body. *See* column 1, lines 36-63 of Levinson. Levinson's "end effector," therefore, includes two sets of cooperating wires that cut and retrieve a lesion. Specifically, device 10 includes an elongated tube 14 and first and second sets of wires 20, 28 slidable relative to tube 14. *See* from column 3, line 64 to column 4, line 3; and column 4, lines 4-16, of Levinson. To cut and retrieve tissue, second set of wires 28 is first extended from the distal end of tube 14 to capture and cut tissue. Thereafter, first set of wires 20 is extended from the distal end of tube 14 to capture the cut tissue in cooperation with second set of wires 28. *See* column 5, lines 39-57 of Levinson. The "end effector" of the Levinson device therefore includes two cooperating sets of wires 20, 28.

In addition, two, separate extensions 34 are used to activate and control first and second sets of wires 20, 28. *See* column 4, lines 45-49, *et seq.*, of Levinson. Thus, the multiple sets of wires 20, 28 and the multiple extensions 34, 34 take up considerable space within the distal end of tube 14. The disposition of these multiple components within the distal end of tube 14 of Levinson may greatly inhibit spraying when flowing fluid through tube 14 to the distal end of tube 14.

Thus, in order for Levinson to provide "a device that allows capturing, cutting *and* retrieving tissue," the "end effector" requires *both first and second sets of wires 20, 28. See* column 2, lines 55-63 (emphasis added). As discussed above, the Office Action asserts that in Levinson "[t]he first set of wires are used for capturing and retrieving the cut tissue and have no affect on the tissue cutting performed by wires 28." *See* page 8 of the Office Action. Even assuming that this is true, which Appellant does not necessarily concede, the "end effector" of Levinson still consists of more than second set of wires 28 which cut the tissue (i.e., the "end effector" of Levinson must consist of more than a snare loop actuated or configured to sever tissue). This is because Levinson discloses that the "end effector" also captures the cut tissue, and states that first set of wires 20 captures the tissue by cooperating with second set of wires 28. Thus, the inclusion of first set of wires 20 in the "end effector" of Levinson materially affects and alters basic and novel characteristics of the claimed snare loop, since first set of wires 20 cooperates with second set of wires 28 to capture cut tissue. It is therefore improper for the Examiner to attempt to parse out and ignore first set of wires 20, inasmuch as wires 20 are a necessary part of the "end effector" of Levinson. For these reasons, Levinson also does not disclose or suggest "an end effector consisting essentially of a snare loop."

To establish a *prima facie* case of obviousness based on a combination or suggestion of prior art, the Examiner "must articulate . . . a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference." M.P.E.P. § 2143.A

(8th edition, Revised September 2006). However, for the above reasons, the combination of Konomura and Levinson does not disclose or suggest at least the claimed features of "an end effector consisting essentially of a snare loop" actuated or configured to sever tissue, as recited in each of independent claims 1, 34, 47 and 59. Therefore, allowance of these independent claims is requested.

(ii). The Combination of Konomura and Levinson Does Not Disclose or Suggest Features Recited in the Dependent Claims

Claims 2-4, 10-18, 28-33, 35-37, 39, 40, 43-46, 48-53, 56, 58, 60-64, 66, 67 and 97-100, which depend from independent claims 1, 34, 47, and 59, are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson. Allowance of these dependent claims is requested at least because, as discussed above, the combination of Konomura and Levinson does not disclose or suggest at least the claimed features of "an end effector consisting essentially of a snare loop" actuated or configured to sever tissue. Each of the dependent claims recites these features. Therefore, allowance of the dependent claims is requested.

(a). Independent Basis for Allowance of Dependent Claims 97-100

Notwithstanding the above discussion, dependent claims 97-100 further recite that "the end effector consists of" the snare loop. As set forth in M.P.E.P. § 2111.03, "[t]he transitional phrase consisting of excludes any element, step or ingredient not specified in the claim." Citing *In re Gray*, 53 F.2d 520 (CCPA 1931) (emphasis added). *See* also *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 1282 (Fed. Cir 1986) ("The district court correctly observed that the phrase consisting of

appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a). The court correctly declined to read this usage of consisting of as excluding all other elements from the claim as a whole.").

As discussed above, neither Konomura nor Levinson discloses or suggests such an end effector. Thus, dependent claims 97-100, which respectively depend from independent claims 1, 34, 47 and 59, are allowable for this independent reason.

B. The Rejection of Dependent Claims 5-7 over Konomura in View of Levinson in Further View of McAlister.

Claims 5-7, which depend from independent claim 1, are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of McAlister. As discussed above, the combination of Konomura and Levinson does not disclose or suggest at least the claimed features of "an end effector consisting essentially of a snare loop" actuated to sever tissue, as recited in independent claim 1. Dependent claims 5-7 recite these features.

McAlister also does not disclose or suggest, and indeed is not relied on in the Office Action to disclose or suggest, such an end effector. Therefore, allowance of dependent claims 5-7 is requested.

C. The Rejection of Claims 69-75, 81, 82, 89, 93 and 101 over Konomura in View of Levinson in Further View of Okada

Claims 69-75, 81, 82, 89, 93 and 101 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of Okada. These claims are allowable for at least the following reasons.

(i). The Combination of Konomura, Levinson and Okada Does Not Disclose or Suggest that "a Portion of the Flow Path Has a Cross-Sectional Flow Area Smaller than Both a Cross-Sectional Flow Area of an Inlet and an Outlet," as Recited in Independent Claim 69

The combination of Konomura, Levinson and Okada does not disclose or suggest at least the claimed features of "at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path," as recited in independent claim 69. This is because none of the references disclose such a flow path, and even if the references did disclose such a flow path, there is no reason or motivation to combine the references with one another.

(a). Discussion of Applicable Law

A claim is obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2000). Two of several factual inquiries underlying this determination are the scope and content of the prior art and the differences between the

claimed invention and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

In determining the differences between the claimed invention and the prior art, the proper analysis under 35 U.S.C. § 103(a) must consider the invention as a whole and not simply the differences themselves. *See* M.P.E.P. § 2141.02 (8th edition, Revised September 2006). Moreover, all the claim limitations must be taken into consideration. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) ("All words in the claim must be considered in judging the patentability of that claim against the prior art.").

The Supreme Court recently reviewed the requirements of a proper obviousness analysis in applying 35 U.S.C. § 103(a) in *KSR Int'l Co. v. TeleFlex Inc.*, 550 U.S. __; No. 04-1350, (April 30, 2007). In that decision, the Supreme Court reiterated that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at p. 15. More specifically, the Court stated that:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason to combine** the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

Id. at p. 14. (emphasis added). Judged by this standard, the Examiner has not met the required burden for establishing obviousness of the claimed invention.

(b). Rejection in the Office Action

In the final Office Action mailed September 5, 2007, the Examiner concedes that the combination of Konomura and Levinson does not disclose the claimed features that

"at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path," as recited in independent claim 69. *See* page 6 of the Office Action. However, the Examiner asserts that Okada, in Figure 30B, discloses this claim feature. The Examiner then concludes that "[i]t would have been obvious . . . to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Okada and is well known in the art." *See* page 7 of the Office Action. Appellant disagrees.

(c). None of the References Disclose or Suggest the Claimed Features

The Office Action has not established that Okada discloses that "at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path." Okada discloses a washing nozzle 372 for cleaning an observation lens of an endoscope. *See* from column 22, line 56 to column 23, line 24. The text of Okada does not describe, however, any cross-sectional areas of washing nozzle 372. The text therefore does not describe that a portion of a flow path of washing nozzle 372 "has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path."

Further, the figures of Okada do not expressly provide information about the relationship between the cross-sectional areas of an inlet, an outlet, and a portion therebetween of washing nozzle 372. Appellant concedes that the figures of Okada,

including Figure 30A and Figure 30B, show that within washing nozzle 372, at least a portion of a flow path has one *dimension* that is smaller than a dimension of an inlet and a dimension on an outlet. *See* Figure 30B in particular. However, the figures do not show whether a portion of the flow path within washing nozzle 372 has a *cross-sectional area* smaller than both a cross-sectional area of an inlet and a cross-sectional area of an outlet of washing nozzle 372. This is because Okada does not describe or illustrate further details of washing nozzle 372. Thus, Okada includes no express teaching of a flow path portion having a cross-sectional area smaller than the cross-sectional areas of the inlet and the outlet.

Moreover, it is not inherent that washing nozzle 372 of Okada includes a portion that "has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path." As set forth in M.P.E.P. 2112 (IV.), "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (emphasis in original). *See* also *In re Oelrich*, 666 F.2d 578, 581-82 (CCPA 1981) ("To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference."). As discussed above, Figures 30A and 30B at most show that one dimension of a flow path is smaller than that dimension at the inlet and the outlet. It is possible that this portion having a smaller dimension actually has a larger cross-sectional area than the inlet and the outlet. Without knowing other dimensions of the flow path, it is not "necessarily" the case that the portion having the smaller dimension has a smaller cross-sectional area.

Thus, none of the references disclose or suggest the claimed features that "at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path." The allowance of independent claim 69 is therefore requested.

(d). No Motivation to Combine References, Regardless of What They Disclose

Even assuming that Okada does disclose the above-discussed flow path, there is still "no apparent reason to combine" Konomura, Levinson and Okada. *KSR* at p. 14.

Konomura discloses forming a fluid passage in the front end tip 7 to enable continuous fluid supply when the end tip 7 closes the front end of the sheath 2. *See* column 4, lines 14-35 of Konomura. Completely different from Konomura, Okada discloses that washing nozzle 372 is used for cleaning the observation lens of the endoscope. *See* from column 22, line 56 to column 23, line 24, of Okada. Inasmuch as Konomura does not disclose an observation lens, and therefore does not require washing of an observation lens, Konomura does not require washing nozzle 372 of Okada or its alleged feature of "greater control over the outputted flow of fluid." Consequently, even if the alleged teaching of Okada were available to one skilled in the art, there is no motivation or reason to have modified the fluid passages of Konomura to employ washing nozzle 372 of Okada.

Further, Konomura's device is for use with a separate endoscope. *See* column 1, lines 5-10. The distal end of an endoscope typically has structure for illuminating and visualizing a treatment site within a patient's body, and includes one or more lumens

into which a device, such as Konomura's, is inserted. In a procedure, an endoscope is first inserted into a patient's body lumen until the scope's distal end reaches a treatment site. Then, the Konomura device is passed within the lumen of the endoscope until it exits the lumen to perform the appropriate treatment at the site. For these reasons, there is no reason for any washing nozzle, including washing nozzle 372 of Okada, to be used with the device of Konomura.

Still further, Okada appears to vary dimensions of washing nozzle 372 to permit washing nozzle 372 to bend close to a cover 327, such that the outlet of washing nozzle 372 is aimed at cover 327. Inasmuch as there is no need to wash a corresponding tip or cover of the device of Konomura, there is no reason to use the so-bent washing nozzle 372 of Okada in the device of Konomura.

Moreover, contrary to the Examiner's allegation, there is no support for the assertion that washing nozzle 372 of Okada provides any "greater control over the outputted flow of fluid" than the flow passages of Konomura. Nor has the Examiner provided any factual basis to support the assertion that such is "well known in the art." In fact, nothing in Okada discloses or even suggests that washing nozzle 372 provides "greater control over the outputted flow of fluid," as alleged by the Examiner.

There is also no support or factual basis for the Examiner's allegation that "[v]arying the nozzle configuration in the device of Konomura and Levinson would aid in the removal of foreign matter from a target site within the body, as providing alternate nozzle configurations (such as those taught by Okada . . .) would allow for greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures." *See* pages 9 and 10 of the Office Action.

The Examiner's asserted combination of references clearly reflects impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, one of ordinary skill in the art would not have combined Konomura, Levinson and Okada to provide the claimed features recited in independent claim 69 simply because there would not have been any reason to do so.

Allowance of this independent claim is therefore requested for this independent reason.

(ii). The Combination of Konomura, Levinson and Okada Does Not Disclose or Suggest Features Recited in the Dependent Claims

Claims 70-75, 81, 82, 89, 93, and 101, which depend from independent claims 47, 59 and 69, are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of Okada. Allowance of these dependent claims is requested at least because, as discussed above with respect to independent claim 69, there is no motivation or reason to combine Konomura, Levinson and Okada to disclose or suggest at least the claimed features that "at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path." Each of the dependent claims recites these features, and, therefore, allowance of those claims is requested.

(a). Independent Basis for Allowance of Dependent Claims 89 and 93

Notwithstanding the above discussion, dependent claims 89 and 93 further recite "an end effector consisting essentially of a snare loop," based on their dependency from claims 47 and 59, respectively. As discussed above, neither Konomura nor Levinson discloses or suggests such an end effector. Okada also does not disclose or suggest, and is not relied on by the Office Action to disclose or suggest, such an end effector. Thus, dependent claims 89 and 93 are allowable for this independent reason.

(b). Independent Basis for Allowance of Dependent Claim 101

Dependent claim 101 further recites that "the end effector consists of" the snare loop. As set forth in M.P.E.P. § 2111.03, "[t]he transitional phrase consisting of excludes any element, step or ingredient not specified in the claim." Citing *In re Gray*, 53 F.2d 520 (CCPA 1931) (emphasis added). As discussed above, none of Konomura, Levinson and Okada disclose or suggest such an end effector. Thus, dependent claim 101, which depends from independent claim 69, is allowable for this independent reason.

D. The Rejection of Claims 87, 88 and 102 over Konomura in View of Levinson in Further View of Termanini

Claims 87, 88 and 102 are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of Termanini. Allowance of these claims is requested for at least the following reasons.

(i). The Combination of Konomura, Levinson and Termanini does not Disclose or Suggest that "the Flow Path Comprises an Inlet and a Plurality of Outlets Connecting to the Inlet," as Recited in Independent Claim 87

The combination of Konomura, Levinson and Termanini does not disclose or suggest at least the claimed features that "the flow path comprises an inlet and a plurality of outlets connecting to the inlet," as recited in independent claim 87. This is because there is no reason or motivation to modify the references to provide such a configuration.

With respect to independent claim 87, there is "no apparent reason to combine" the teachings of the applied references. *KSR* at p. 14. Specifically, there is no reason in the references, or elsewhere, to modify Konomura, Levinson and Termanini to provide the claimed features that "the flow path comprises an inlet and a plurality of outlets connecting to the inlet," as recited in independent claim 87.

In the final Office Action mailed September 5, 2007, the Examiner concedes that the combination of Konomura and Levinson does not disclose these features. *See* page 7 of the Office Action. However, the Examiner asserts that Termanini discloses "an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7)." *See* page 8 of the Office Action. Thus, the Examiner seems to assert that Termanini discloses the claimed features that "the flow path comprises an inlet and a plurality of outlets connecting to the inlet," as recited in independent claim 87. The Examiner then concludes that "[i]t would have been obvious . . . to vary the outlet area in the apparatus of Konomura and

Levinson in order to have greater control over the outputted flow of fluid as taught by Termanini and is well known in the art." *See* page 8 of the Office Action. Appellant disagrees.

Termanini discloses a fiber-optic catheter 12 for visual inspection of the cardiovascular system. *See* column 2, lines 49-52. Catheter 12 includes a spray head 36 for dispersing liquid into the bloodstream to displace the blood with the clear saline for improved viewing of the vessels and organs within the cardiovascular system. *See* column 4, lines 25-50. However, one of ordinary skill in the art would not have combined the alleged teachings of the references as proposed by the Examiner.

First, the purpose of the fluid passage in distal tip 7 of Konomura is to permit a continuous supply of fluid when the end of sheath 2 is closed with distal tip 7. *See* column 4, lines 14-35, of Konomura. Thus, this fluid passage need only allow a desired amount of fluid to be fed therethrough. Nothing in Konomura suggests the need for dispersing fluid or "greater control over the outputted flow of fluid," as the Examiner alleges. So, even if the alleged teaching of Termanini were available to one skilled in the art, he or she would not have modified the fluid passages of Konomura to employ spray head 36 of Termanini.

Moreover, modifying distal tip 7 of Konomura to have a plurality of apertures, as allegedly taught by Termanini, would not serve any purpose other than complicating the design of distal tip 7 of Konomura and unnecessarily requiring increased fluid pressure for injection of fluid across distal tip 7 of Konomura. Such adverse effects would have sufficiently deterred one of ordinary skill in the art from modifying distal tip 7 of Konomura to employ spray head 36 of Termanini.

Further, contrary to the Examiner's allegation, spray head 36 of Termanini does not teach any "greater control over the outputted flow of fluid" than the flow passages of Konomura. Nor has the Examiner provided any factual basis to support his allegation that such is "well known in the art." Spray head 36 is to inject saline solution into the bloodstream to displace blood medium around it. Nothing in Termanini teaches or suggests that its spray head 36 provides "greater control over the outputted flow of fluid."

There is also no support or factual basis for the Examiner's allegation that "[v]arying the nozzle configuration in the device of Konomura and Levinson would aid in the removal of foreign matter from a target site within the body, as providing alternate nozzle configurations (such as those taught by . . . Termanini) would allow for greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures." *See* pages 9 and 10 of the Office Action.

The Examiner's asserted combination of the cited references reflects impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, one of ordinary skill in the art would not have combined the teachings of Konomura and Termanini in the manner proposed by the Examiner because there is no reason to do so.

Thus, there is no motivation or reason to combine Konomura, Levinson and Termanini to disclose or suggest at least the claimed features that "the flow path comprises an inlet and a plurality of outlets connecting to the inlet," as recited in independent claim 87. Allowance of this independent claim is therefore requested.

(ii). The Combination of Konomura, Levinson and Termanini Does Not Disclose or Suggest Features Recited in the Dependent Claims

Claims 88 and 102, which depend from independent claim 87, are rejected under 35 U.S.C. § 103(a) as unpatentable over Konomura in view of Levinson in further view of Termanini. Allowance of these claims is requested at least because, as discussed above with respect to independent claim 87, there is no motivation or reason to combine Konomura, Levinson and Termanini to disclose or suggest at least the claimed features that "the flow path comprises an inlet and a plurality of outlets connecting to the inlet." Dependent claims 88 and 102 recites these features. Allowance of these dependent claims is therefore requested.

(a). Independent Basis for Allowance of Dependent Claim 102

Notwithstanding the above discussion, dependent claim 102 further recites that "the end effector consists of" the snare loop. As set forth in M.P.E.P. § 2111.03, "[t]he transitional phrase consisting of excludes any element, step or ingredient not specified in the claim." Citing *In re Gray*, 53 F.2d 520 (CCPA 1931) (emphasis added). As discussed above, neither Konomura nor Levinson discloses or suggests such an end effector. Termanini also does not disclose or suggest, and is not relied on by the Office Action to disclose or suggest, such an end effector. Thus, dependent claim 102 is allowable for this independent reason.

Conclusion

For the reasons given above, the allowance of rejected claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93 and 97-102 is therefore requested.

Further, withdrawn claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92 and 94-96 depend from the above-identified allowed claims, and are therefore allowable for at least the same reasons. Consideration on the merits, and the allowance of these withdrawn claims, is requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 2, 2008

By: 

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Claims Appendix

1. (Previously Presented) A medical device comprising:

a proximal handle;

an elongated member having a proximal end, a distal end, and a lumen therebetween, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body;

an end effector consisting essentially of a snare loop proximate the distal end of the elongated member, actuation of the proximal handle causing the snare loop to sever tissue; and

a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member.

2. (Original) The device of claim 1, wherein the flow path defined by the distal member has a cross-sectional flow area less than a cross-sectional flow area of the lumen.

3. (Original) The device of claim 1, wherein the handle includes a port in fluid communication with the lumen.

4. (Original) The device of claim 3, further comprising a fluid supplying member for supplying fluid to the port.

5. (Previously Presented) The device of claim 4, wherein the port includes an interlocking member configured to engage with the fluid supplying member.

6. (Original) The device of claim 4, wherein the fluid supplying member includes a syringe.

7. (Original) The device of claim 3, wherein the handle defines a fluid chamber sealed from a portion of the handle and for providing a passage of fluid from the port to the lumen.

8. and 9. (Canceled)

10. (Previously Presented) The device of claim 1, wherein the distal member includes a sealing member to seal the lumen.

11. (Previously Presented) The device of claim 1, wherein at least a portion of the distal member has a frusto-conical shape for substantially closing the lumen.

12. (Previously Presented) The device of claim 1, wherein the distal member includes a base portion and a head portion, the base portion having an outer diameter

substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen.

13. (Previously Presented) The device of claim 1, wherein the distal member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen.

14. (Original) The device of claim 1, wherein the flow path of the distal member has a varying cross-sectional flow area along the flow path.

15. (Original) The device of claim 14, wherein at least a portion of the flow path has a cross-sectional flow area smaller than that of at least one of an inlet and an outlet of the flow path.

16. (Original) The device of claim 1, wherein the distal member connects to the end effector.

17. (Original) The device of claim 16, wherein the distal member connects to the end effector at a distal end of the end effector.

18. (Original) The device of claim 17, wherein the distal member is movable relative to the lumen and is configured to substantially close the lumen when the end

effector retracts proximally into the lumen and to open the lumen when the end effector extends distally out of the lumen.

19. (Withdrawn) The device of claim 1, wherein the distal member fixedly connects to the end effector at a proximal end of the end effector.

20. (Withdrawn) The device of claim 19, wherein the distal member includes a main body connected to the proximal end of the end effector and an annular flange extending from an outer surface of the main body, wherein the annular flange has an outer diameter substantially the same as the inner diameter of the elongated member.

21. (Withdrawn) The device of claim 20, wherein the flow path is formed in the annular flange.

22. (Canceled)

23. (Withdrawn) The device of claim 1, wherein the distal member includes:

a main body fixedly connected to a proximal end of the end effector; and

an annular body fixed to the distal end of the elongated member.

24. (Withdrawn) The device of claim 23, wherein the annular body includes a first portion extending internally from an inner surface of the annular body.

25. (Withdrawn) The device of claim 24, wherein the main body and the first portion are configured to contact each other to substantially close the lumen of the elongated member.

26. (Withdrawn) The device of claim 23, wherein the flow path has an inlet opening in a direction transverse to an axis of the annular body and an outlet opening in a direction substantially parallel to the axis of the annular body.

27. (Withdrawn) The device of claim 23, wherein the annular body has a stepped portion for securing the annular body to the elongated member.

28. (Original) The device of claim 1, wherein the handle includes a stationary part and a movable part movable relative to the stationary part.

29. (Previously Presented) The device of claim 28, wherein movement of the movable part relative to the stationary part causes the distal member to sealingly engage the distal end of the lumen so that the lumen is in fluid communication with the outside of the elongated member via the flow path of the distal member.

30. (Previously Presented) The device of claim 29, further comprising a control member having a proximal end coupled to the movable part and a distal end coupled to the end effector so that actuation of the movable part relative to the stationary part enables movement of the end effector to sever tissue.

31. (Original) The device of claim 1, wherein the handle includes an electrical connector for receiving cautery current from a power supply source.

32. (Original) The device of claim 31, wherein the electrical connector is electrically connected to the end effector.

33. (Original) The device of claim 1, wherein the distal member defines a plurality of flow paths.

34. (Previously Presented) A medical device comprising:

an elongated member having a proximal end, a distal end, and a lumen therethrough, the elongated member being sufficiently flexible to traverse through a tortuous anatomy of a patient's body;

an end effector consisting essentially of a snare loop proximate the distal end of the elongated member, said end effector configured to sever tissue; and

a nozzle member configured to substantially seal the distal end of the lumen, the nozzle member defining a flow path in fluid communication between the lumen and an outside of the elongated member when the distal end of the lumen is sealed with the nozzle member.

35. (Original) The device of claim 34, wherein the flow path has a flow area that is smaller than a flow area of the lumen.

36. (Original) The device of claim 34, further comprising a handle proximate the distal end of the elongated member and including a port.

37. (Original) The device of claim 34, wherein the nozzle member is configured to selectively seal the distal end of the lumen.

38. (Canceled)

39. (Original) The device of claim 34, wherein the nozzle member connects to the end effector.

40. (Original) The device of claim 39, wherein the nozzle member connects to the end effector at a distal end of the end effector.

41. (Withdrawn) The device of claim 39, wherein the nozzle member connects to the end effector at a proximal end of the end effector.

42. (Withdrawn) The device of claim 34, wherein the nozzle member comprises a first member fixedly connected to a proximal end of the end effector and a second member fixedly connected to a distal end of the elongated member, wherein the first and second members are configured to contact one another so as to substantially seal the distal end of the lumen.

43. (Original) The device of claim 34, further comprising a handle proximate the proximal end of the elongated member, the handle configured to control movement of the end effector and the nozzle member relative to the elongated member.

44. (Original) The device of claim 43, further comprising a control member extending between the handle and at least one of the end effector and the nozzle member.

45. (Original) The device of claim 43, wherein the handle includes a connector for receiving cautery current from a power supply source, the connector electrically connected to the end effector.

46. (Original) The device of claim 34, wherein the nozzle member defines a plurality of flow paths.

47. (Previously Presented) A method of performing a medical procedure, the method comprising:

inserting a medical device into a tissue tract of a patient, the medical device comprising a lumen and a nozzle member configured to substantially seal a distal end of the lumen, the nozzle member defining a flow path in fluid communication between the lumen and an outside of the lumen when the distal end of the lumen is sealed with the nozzle member, the medical device further comprising an end effector consisting essentially of a snare loop coupled to the nozzle member;

closing the distal end of the lumen with the nozzle member,

spraying fluid through the flow path of the nozzle member and onto tissue of the tissue tract to enhance visualization of tissue of the tissue tract; and

actuating the end effector of the medical device to sever the tissue of the tissue tract.

48. (Original) The method of claim 47, further comprising inserting an endoscope for viewing the tissue tract.

49. (Original) The method of claim 47, wherein the medical procedure is a colonoscopic polypectomy procedure.

50. (Original) The method of claim 47, further comprising supplying fluid to the medical device.

51. (Original) The method of claim 47, wherein spraying fluid includes spraying a chromoscopic dye agent.

52. (Original) The method of claim 47, wherein spraying fluid includes spraying a radiographic contrast agent.

53. (Original) The method of claim 47, further comprising supplying cautery current to the end effector.

54. and 55. (Canceled)

56. (Previously Presented) The method of claim 47, wherein the nozzle member connects to the end effector.

57. (Withdrawn) The method of claim 47, wherein the nozzle member is fixedly connected to a distal end of the lumen.

58. (Original) The method of claim 47, wherein the medical procedure includes removing tissue from the tissue tract.

59. (Previously Presented) A method of performing a medical procedure, the method comprising:

inserting a medical device into a patient, the medical device comprising:

an elongated member having a proximal end, a distal end, and a lumen therethrough, the distal end extending into the patient;

an end effector consisting essentially of a snare loop proximate the distal end of the elongated member; and

a distal member coupled to the end effector and configured to substantially seal the distal end of the lumen, the distal member defining a flow path in fluid communication between the lumen and an outside of the elongated member when the lumen is sealed with the distal member;

injecting fluid through the distal member of the medical device; and

actuating the end effector to sever tissue of a tissue tract.

60. (Previously Presented) The method of claim 59, further comprising injecting fluid through the lumen of the medical device when the lumen is not sealed with the distal member.

61. (Previously Presented) The method of claim 59, wherein:

inserting the medical device includes inserting the medical device into the tissue tract of a patient;

injecting fluid includes injecting a contrast agent for enhancing visualization of tissue in the tissue tract; and

actuating the end effector includes removing tissue from the tissue tract.

62. (Original) The method of claim 59, further comprising inserting an endoscope for viewing the tissue tract.

63. (Original) The method of claim 59, further comprising supplying fluid to the lumen of the medical device.

64. (Original) The method of claim 59, further comprising supplying cautery current to the end effector.

65. (Canceled)

66. (Original) The method of claim 59, wherein the flow path of the distal member has a flow area that is smaller than a flow area of the lumen.

67. (Original) The method of claim 59, wherein the distal member connects to the end effector.

68. (Withdrawn) The method of claim 59, wherein the distal member is fixedly connected to the distal end of the elongated member.

69. (Previously Presented) A medical device comprising:

a proximal handle;

an elongated member having a proximal end, a distal end, and a lumen therebetween, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body;

an end effector proximate the distal end of the elongated member, actuation of the proximal handle causing the end effector to perform a medical procedure; and

a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member,

wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.

70. (Previously Presented) The device of claim 69, wherein the handle includes a port in fluid communication with the lumen.

71. (Previously Presented) The device of claim 69, wherein the end effector comprises a tissue cutting end effector.

72. (Previously Presented) The device of claim 69, wherein the distal member includes a base portion and a head portion, the base portion having an outer diameter substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen.

73. (Previously Presented) The device of claim 69, wherein the distal member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen.

74. (Previously Presented) The device of claim 69, wherein the distal member connects to the end effector at a distal end of the end effector.

75. (Previously Presented) The device of claim 74, wherein the distal member is movable relative to the lumen and is configured to substantially close the lumen when the end effector retracts proximally into the lumen and to open the lumen when the end effector extends distally out of the lumen.

76. (Withdrawn) The device of claim 69, wherein the distal member connects to the end effector at a proximal end of the end effector.

77. (Withdrawn) The device of claim 76, wherein the distal member includes a main body connected to the proximal end of the end effector and an annular flange extending from an outer surface of the main body, wherein the annular flange has an outer diameter substantially the same as the inner diameter of the elongated member.

78. (Withdrawn) The device of claim 69, wherein the distal member includes a main body connected to a proximal end of the end effector and an annular body fixed to the distal end of the elongated member.

79. (Withdrawn) The device of claim 78, wherein the annular body includes a first portion extending internally from an inner surface of the annular body and being configured to contact a portion of the main body to substantially close the lumen of the elongated member.

80. (Withdrawn) The device of claim 78, wherein the flow path has an inlet opening in a direction transverse to an axis of the annular body and an outlet opening in a direction substantially parallel to the axis of the annular body.

81. (Previously Presented) The device of claim 69, wherein the handle includes an electrical connector for receiving cautery current from a power supply source.

82. (Previously Presented) The device of claim 69, wherein the distal member defines a plurality of flow paths.

83. (Withdrawn) The device of claim 1, wherein the distal member comprises:

a main body connected to a proximal end of the end effector; and

an annular body fixed to the distal end of the elongated member, and

wherein the main body and the annular body are configured to contact each other to substantially close the distal end of the lumen.

84. (Withdrawn) The device of claim 83, wherein the annular body includes a first portion extending internally from an inner surface of the annular body.

85. (Withdrawn) The device of claim 84, wherein the main body and the first portion are configured to contact each other to substantially close the lumen of the elongated member.

86. (Withdrawn) The device of claim 83, wherein the flow path has an inlet opening in a direction transverse to an axis of the annular body and an outlet opening in a direction substantially parallel to the axis of the annular body.

87. (Previously Presented) A medical device comprising:

a proximal handle;

an elongated member having a proximal end, a distal end, and a lumen therebetween, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body;

an end effector proximate the distal end of the elongated member, actuation of the proximal handle causing the end effector to perform a medical procedure; and

a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member,

wherein the flow path comprises an inlet and a plurality of outlets connecting to the inlet.

88. (Previously Presented) The device of claim 87, wherein the end effector comprises a tissue cutting end effector.

89. (Previously Presented) The method of claim 47, wherein at least a portion of the flow path in the nozzle member has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.

90. (Withdrawn) The method of claim 47, wherein the nozzle member is fixedly connected to a proximal end of the end effector.

91. (Withdrawn) The method of claim 47, wherein the nozzle member includes a main body connected to a proximal end of the end effector and an annular body fixed to the distal end of the lumen.

92. (Withdrawn) The method of claim 91, wherein the annular body includes a first portion extending internally from an inner surface of the annular body and being configured to contact a portion of the main body to substantially close the lumen of the elongated member.

93. (Previously Presented) The method of claim 59, wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.

94. (Withdrawn) The method of claim 59, wherein the distal member is fixedly connected to a proximal end of the lumen.

95. (Withdrawn) The method of claim 59, wherein the distal member includes a main body connected to a proximal end of the end effector and an annular body fixed to the distal end of the elongated member.

96. (Withdrawn) The method of claim 95, wherein the annular body includes a first portion extending internally from an inner surface of the annular body and being configured to contact a portion of the main body to substantially close the lumen of the elongated member.

97. (Previously Presented) The device of claim 1, wherein the end effector consists of a snare loop.

98. (Previously Presented) The device of claim 34, wherein the end effector consists of a snare loop.

99. (Previously Presented) The method of claim 47, wherein the end effector consists of a snare loop.

100. (Previously Presented) The method of claim 59, wherein the end effector consists of a snare loop.

101. (Previously Presented) The device of claim 71, wherein the end effector consists essentially of a snare loop.

102. (Previously Presented) The device of claim 88, wherein the end effector consists essentially of a snare loop.

Evidence Appendix

None

Related Proceedings Appendix

None